IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

Gene Schurman,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 3:15-cv-1180
	)	
JANSSEN PHARMACEUTICALS, INC.	)	
a Pennsylvania corporation,	)	**JURY TRIAL DEMANDED**
Serve: CT Corporation System	)	
208 S. LaSalle St., Suite 814	)	
Chicago, IL 60604	)	
	)	
and	)	
	)	
JOHNSON & JOHNSON CO.,	)	
a New Jersey corporation	)	
Serve: One Johnson & Johnson Plaza	)	
New Brunswick, NJ 08933	)	
	)	
and	)	
	)	
MITSUBISHI TANABE PHARMA CORP.,	)	
a Japanese corporation,	)	
Serve: 3-2-10, Dosho-machi, Chuo-ku	)	
Osaka 541-8505, Japan	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Gene Schurman, (hereinafter "Plaintiff"), by and through his undersigned counsel, brings this action seeking judgment against Janssen Pharmaceuticals, Inc., Johnson & Johnson Co., and Mitsubishi Tanabe Pharma Corp. (collectively referred to as "Defendants") for injuries and damages caused by Plaintiff's ingestion of INVOKANA, a drug in the *gliflozin* class.

INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold INVOKANA for the treatment of diabetes.

2. Defendants concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including stroke, heart attack, severe kidney damage, and diabetic ketoacidosis.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed severe kidney damage. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff.

5. This is an action for product liability, design defect, failure to warn, negligence, fraud, misrepresentation, and breach of warranties against Mitsubishi Tanabe Pharma Corp. ("TANABE"), Johnson & Johnson, Co ("JOHNSON & JOHNSON"), and Janssen Pharmaceuticals ("JANSSEN").

6. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

7. At all times relevant hereto, Plaintiff Gene Schurman was a resident and citizen of Breese, Illinois, located in Clinton County, and was prescribed, purchased, ingested, and exposed to INVOKANA in Clinton County, Illinois. As a result of ingesting INVOKANA, Plaintiff Gene Schurman suffered personal and economic injuries, which developed and occurred in Clinton County, Illinois, and he sought treatment for the effects attendant thereto in Clinton County, Illinois and St. Clair County, Illinois.

8. Defendant JANSSEN is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN is registered to do business in Illinois, and has designated a registered agent in Illinois. JANSSEN is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

9. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

10. Defendant TANABE is a Japanese corporation with its principal place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan. TANABE is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling

marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 USC § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides.

12. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including INVOKANA, within the State of Illinois, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

13. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and misleading information about INVOKANA to health care professionals in the State of Illinois, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Illinois.

14. Defendants engage in substantial business activities in the State of Illinois. At all relevant times, Defendants transacted, solicited, and conducted business in Illinois through their employees, agents, and/or sales representatives and derived substantial revenue from such business in Illinois.

15. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Illinois. As such, this Court has personal jurisdiction over all Defendants.

16. Venue of this case is proper in the Southern District of Illinois pursuant to 28 U.S.C. § 1391(b)(1) because all Defendants are residents of this state.

17. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the Southern District of Illinois.

FACTUAL BACKGROUND

18. Defendant TANABE, in collaboration with Defendant JOHNSON & JOHNSON, designed and developed the diabetes drug, INVOKANA.

19. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, acquired the marketing rights to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in the United States, including in the State of Illinois.

20. INVOKANA is one of Defendants' top selling drugs, with sales of $278 million in just the first quarter of 2015.

21. In March 2013, the United States Food and Drug Administration ("FDA") approved Defendants' compound INVOKANA (*canagliflozin*) for the treatment of type 2 diabetes.

22. *Canagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 ("SGLT2") inhibitors, and is marketed in the United States by Defendants under the name INVOKANA.

23. SGLT2 inhibitors, including INVOKANA, primarily are used for treating type 2 diabetes. INVOKANA was the first SGLT2 inhibitor approved for use by the FDA.

24. SGLT2 inhibitors, including INVOKANA, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not

metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

25. Though INVOKANA is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continue to market INVOKANA for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

26. Since INVOKANA's release, the FDA has received a significant number of reports of severe kidney damage among users of INVOKANA.

27. An analysis of the FDA adverse event database shows that patients taking INVOKANA are several times more likely to report severe kidney damage than those taking non-SGLT2 diabetes drugs to treat diabetes.

28. Despite Defendants' knowledge of the increased risk of severe injury among INVOKANA users, Defendants did not warn patients but instead continued to defend INVOKANA, mislead physicians and the public, and minimize unfavorable findings.

29. Consumers, including Plaintiff, who have used INVOKANA for treatment of diabetes, have several alternative safer products available to treat the conditions.

30. Defendants knew of the significant risk of kidney damage caused by ingestion of INVOKANA. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity such risks.

31. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of INVOKANA and willfully deceived Plaintiff, his health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the INVOKANA.

32. As a direct result, in or about September 2013, Plaintiff was prescribed and began taking INVOKANA, primarily to treat diabetes.

33. Plaintiff ingested and used INVOKANA as prescribed and in a foreseeable manner.

34. The INVOKANA used by Plaintiff was provided to him in a condition substantially the same as the condition in which it was manufactured and sold.

35. Plaintiff agreed to initiate treatment with INVOKANA in an effort to reduce his blood sugar. In doing so, Plaintiff relied on claims made by Defendants that INVOKANA was safe and effective for the treatment of diabetes.

36. Instead, INVOKANA can cause severe injuries, including severe kidney damage.

37. After beginning treatment INVOKANA, and as a direct and proximate result thereof, Plaintiff suffered severe kidney damage.

38. Defendants knew or should have known the risks associated with the use of INVOKANA, including the risk of developing severe kidney damage.

39. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of INVOKANA. This conduct, as well as the product defects complained of herein, were substantial factors in bringing about and exacerbating Plaintiff's injuries.

40. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and INVOKANA's defects.

41. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold INVOKANA without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

42. Plaintiff would not have used INVOKANA had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with INVOKANA, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting INVOKANA.

43. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking INVOKANA.

44. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

45. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

46. Plaintiff has suffered from mental anguish from the knowledge that he may suffer life-long complications as a result of the injuries caused by INVOKANA.

COUNT I
PRODUCT LIABILITY – DESIGN DEFECT (STRICT LIABILITY)

47. Plaintiff restates the allegations set forth above as if fully rewritten herein.

48. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed INVOKANA, including the INVOKANA used by Plaintiff, which was in a defective and unreasonably dangerous condition.

49. Defendants expected INVOKANA to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

50. At all times relevant hereto, Defendants' INVOKANA was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

51. At all times relevant to this action, INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

a. When placed in the stream of commerce, INVOKANA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes;

c. INVOKANA was insufficiently tested;

d. INVOKANA caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time INVOKANA was marketed that ingestion of INVOKANA would result in an increased risk of severe kidney damage, and other injuries;

f. Inadequate post-marketing surveillance; and/or

g. There were safer alternative designs and formulations that were not utilized.

52. INVOKANA was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

53. INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with INVOKANA's design or formulation.

54. INVOKANA, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

55. At all times relevant to this action, Defendants knew or had reason to know that INVOKANA was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

56. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and

otherwise ensure that INVOKANA was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

57. When Defendants placed INVOKANA into the stream of commerce, they knew it would be prescribed to treat diabetes, and they marketed and promoted INVOKANA as safe for treating diabetes.

58. Plaintiff was prescribed, purchased, and used INVOKANA. Plaintiff used INVOKANA for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants

59. Neither Plaintiff nor his health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with INVOKANA before Plaintiff's ingestion of INVOKANA.

60. The harm caused by INVOKANA far outweighed its benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed INVOKANA to make it less dangerous. When Defendants designed INVOKANA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

61. At the time INVOKANA left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or intended function of INVOKANA. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

62. Defendants' defective design of INVOKANA was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of INVOKANA.

Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of INVOKANA.

63. The defects in INVOKANA were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

64. Due to the unreasonably dangerous condition of INVOKANA, Defendants are liable to Plaintiff.

65. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff, with knowledge of the safety problems associated with INVOKANA, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

66. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
PRODUCTS LIABILITY – FAILURE TO WARN (STRICT LIABILITY)

67. Plaintiff restates the allegations set forth above as if fully rewritten herein.

68. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing INVOKANA. Through that conduct, Defendants knowingly and intentionally placed INVOKANA into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, who ingested it.

69. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released INVOKANA into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted INVOKANA to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of INVOKANA.

70. Defendants expected INVOKANA to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff and his prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

71. INVOKANA, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

72. INVOKANA was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. INVOKANA contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with INVOKANA, including the development of Plaintiff's injuries.

73. This defect caused serious injury to Plaintiff, who used INVOKANA for its intended purpose and in a reasonably anticipated manner.

74. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure INVOKANA did not cause users to suffer from unreasonable and dangerous risks.

75. Defendants negligently and recklessly labeled, distributed, and promoted INVOKANA.

76. Defendants had a continuing duty to warn Plaintiff of the dangers associated with INVOKANA.

77. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

78. Plaintiff could not have discovered any defects in INVOKANA through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

79. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that INVOKANA caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks

associated with its use. The dangerous propensities of INVOKANA, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

80. INVOKANA, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

81. Each of the Defendants knew or should have known that the limited warnings disseminated with INVOKANA were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

82. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of INVOKANA;

b. continued to aggressively promote INVOKANA even after Defendants knew or should have known of the unreasonable risks from use;

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of INVOKANA's effect on renal function;

e. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment; and

f. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of INVOKANA.

83. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of INVOKANA.

84. Due to these deficiencies and inadequacies, INVOKANA was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

85. Had Defendants properly disclosed and disseminated the risks associated with INVOKANA, Plaintiff would have avoided the risk of developing injuries as alleged herein.

86. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of INVOKANA and the risks associated with its use.

87. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE

88. Plaintiff restates the allegations set forth above as if fully rewritten herein.

89. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk.

Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and his healthcare providers.

90. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

91. Plaintiff therefore asserts claims for exemplary damages.

92. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

93. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of INVOKANA. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of INVOKANA, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting INVOKANA, despite their knowledge and awareness of these serious side effects and risks.

94. Defendants had knowledge of, and were in possession of evidence demonstrating that INVOKANA caused serious side effects. Notwithstanding Defendants' knowledge,

Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of INVOKANA.

95. Although Defendants knew or recklessly disregarded the fact that INVOKANA causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute INVOKANA to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

96. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing INVOKANA and consumers from purchasing and ingesting INVOKANA, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming INVOKANA.

97. Defendants knew of INVOKANA's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by INVOKANA.

98. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other INVOKANA users and for the primary purpose of increasing Defendants' profits from the sale and distribution of INVOKANA. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

99. Prior to the manufacture, sale, and distribution of INVOKANA, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the

medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of INVOKANA to risk of injury or death.

100. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in INVOKANA and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of INVOKANA knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

101. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IV
NEGLIGENCE

102. Plaintiff restates the allegations set forth above as if fully rewritten herein.

103. Defendants directly or indirectly caused INVOKANA to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

104. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling

INVOKANA, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with INVOKANA.

105. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of INVOKANA.

106. Defendants had a duty to disclose to health care professionals the causal relationship or association of INVOKANA to the development of Plaintiff's injuries.

107. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of INVOKANA, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of INVOKANA, including the injuries suffered by Plaintiff.

108. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold INVOKANA, Defendants knew, or in the exercise of reasonable care should have known, that their product was defective, dangerous, and otherwise harmful to Plaintiff.

109. Defendants knew, or in the exercise of reasonable care should have known, that the use of INVOKANA could cause or be associated with Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to users of the products.

110. Defendants knew that many health care professionals were prescribing INVOKANA, and that many patients developed serious side effects including but not limited to severe kidney damage.

111. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of INVOKANA in interstate commerce, in that Defendants knew and had reason to know that a consumer's use and ingestion of INVOKANA created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

112. Defendants were further negligent in that they manufactured and produced a defective product containing *canagliflozin*, knew and were aware of the defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the products, and failed to provide adequate warnings of the product's defects and risks.

113. The Defendants' failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test INVOKANA before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of INVOKANA;

c. failing to conduct sufficient post-market testing and surveillance of INVOKANA;

d. designing, manufacturing, marketing, advertising, distributing, and selling INVOKANA to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of INVOKANA and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of INVOKANA and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of INVOKANA's effect on renal function;

g. failing to adequately warn users, consumers, and physicians about the need to monitor renal function in patients that do not already suffer from renal impairment;

h. failing to exercise due care when advertising and promoting INVOKANA; and

i. negligently continuing to manufacture, market, advertise, and distribute INVOKANA after the Defendants knew or should have known of its adverse effects.

114. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution and sale of INVOKANA.

115. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of INVOKANA.

116. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

117. Defendants' conduct, as described above, was reckless. Defendants' actions and inaction risked the lives of consumers and users of their products, including Plaintiff.

118. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT V
BREACH OF EXPRESS WARRANTY

119. Plaintiff restates the allegations set forth above as if fully rewritten herein.

120. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing INVOKANA, which is unreasonably dangerous and defective, thereby placing INVOKANA into the stream of commerce.

121. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that INVOKANA:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects, and

d. had been adequately tested and found to be safe and effective for the treatment of diabetes.

122. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with use of INVOKANA. In fact, Defendants knew or should have known that the risks identified in INVOKANA's prescribing information and package inserts do not accurately or adequately set forth the drug's true risks. Despite this, Defendants expressly warranted INVOKANA as safe and effective for use.

123. Defendants advertised, labeled, marketed, and promoted INVOKANA, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce INVOKANA's purchase or use, thereby making an express warranty that INVOKANA would conform to the representations. More specifically, the prescribing information for INVOKANA did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

124. Despite this, Defendants expressly represented that INVOKANA was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and his health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurately nor adequately set forth.

125. The representations about INVOKANA contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

126. INVOKANA does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries. Therefore, Defendants breached the aforementioned warranties.

127. At all relevant times, INVOKANA did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

128. Neither Plaintiff nor his prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning INVOKANA.

129. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting INVOKANA.

130. Had the prescribing information for INVOKANA accurately and adequately set forth the true risks associated with the use of such product, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

131. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff

also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VI
BREACH OF IMPLIED WARRANTY

132. Plaintiff restates the allegations set forth above as if fully rewritten herein.

133. Defendants manufactured, distributed, advertised, promoted, and sold INVOKANA.

134. At all relevant times, Defendants knew of the use for which INVOKANA was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

135. Defendants were aware that consumers, including Plaintiff, would use INVOKANA for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

136. INVOKANA was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that INVOKANA has dangerous propensities when used as intended and can cause serious injuries, including stroke, heart attack, ketoacidosis, and severe kidney damage.

137. At all relevant times, Defendants intended that INVOKANA be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that INVOKANA was not adequately tested.

138. Defendants were aware that consumers, including Plaintiff, would use INVOKANA as marketed by Defendants. As such, Plaintiff was a foreseeable user of INVOKANA.

139. Upon information and belief, Plaintiff and/or his health care professionals were at all relevant times in privity with Defendants.

140. INVOKANA was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

141. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell INVOKANA only if it was indeed of merchantable quality and safe and fit for its intended use.

142. Defendants breached their implied warranty to consumers, including Plaintiff. INVOKANA was not of merchantable quality, nor was it safe and fit for its intended use.

143. Plaintiff and his physicians reasonably relied upon Defendants' implied warranty for INVOKANA when prescribing and ingesting INVOKANA.

144. Plaintiff's use of INVOKANA was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

145. INVOKANA was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

146. Defendants breached the warranties of merchantability and fitness for its particular purpose because INVOKANA was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

147. The harm caused by INVOKANA far outweighed its alleged benefit, rendering INVOKANA more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

148. Neither Plaintiff nor his health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with INVOKANA.

149. Defendants' breach of these implied warranties caused Plaintiff's injuries.

150. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VII
FRAUDULENT MISREPRESENTATION

151. Plaintiff restates the allegations set forth above as if fully rewritten herein.

152. Defendants made fraudulent misrepresentations with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications.

153. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of INVOKANA to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

154. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and his physicians, rely upon them.

155. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of INVOKANA.

156. Plaintiff, his doctors, and others relied upon these representations.

157. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and

services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT VIII
NEGLIGENT MISREPRESENTATION

158. Plaintiff restates the allegations set forth above as if fully rewritten herein.

159. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning INVOKANA, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

160. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of INVOKANA with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest INVOKANA.

161. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals and consumers of INVOKANA rely on information disseminated and marketed to

them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting INVOKANA.

162. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of INVOKANA were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

163. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, knew or reasonably should have known that health care professionals would write prescriptions for INVOKANA in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for INVOKANA would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

164. From the time INVOKANA was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of INVOKANA. Defendants made material misrepresentations to Plaintiff, his health care professionals, the healthcare community, and the general public, including:

a. stating that INVOKANA had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior alternative drug therapies; and

c. misrepresenting INVOKANA's risk of unreasonable, dangerous, adverse side effects.

165. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

166. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

167. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of INVOKANA.

168. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that INVOKANA had been tested and found to be safe and effective for treating diabetes.

169. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

170. Defendants failed to exercise ordinary care in making their representations concerning INVOKANA and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of INVOKANA.

171. Defendants engaged in a nationwide marketing campaign, over-promoting INVOKANA in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of INVOKANA while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of INVOKANA, when compared to comparable or superior

alternative drug therapies. Defendants negligently misrepresented INVOKANA's risk of unreasonable and dangerous adverse side effects.

172. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

173. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IX
NEGLIGENT DESIGN

174. Plaintiff restates the allegations set forth above as if fully rewritten herein.

175. At all relevant times, Defendants owed a duty to consumers, including Plaintiff and his health care professionals, to exercise reasonable care in the design of INVOKANA.

176. Defendants negligently and carelessly breached this duty of care to Plaintiff because INVOKANA was and is unreasonably defective in design as follows:

a. INVOKANA unreasonably increased the risks of developing Plaintiff's injuries as complained of herein;

b. INVOKANA was not reasonably safe as intended to be used;

c. INVOKANA was more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

d. INVOKANA contained insufficient, incorrect, and defective warnings in that it failed to alert health care professionals and users, including Plaintiff, of the severity of the risks of adverse effects;

e. INVOKANA was not safe for its intended use;

f. INVOKANA was not adequately tested; and/or

g. INVOKANA's risks exceeded any benefit of the drug;

177. Defendants' INVOKANA was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

178. At all times relevant hereto, INVOKANA was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

179. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common intended use.

180. Plaintiff used INVOKANA for its intended purposes and in a manner normally intended: to primarily treat diabetes.

181. The harm caused by INVOKANA far outweighed the benefits, rendering the INVOKANA more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed INVOKANA to make it less dangerous. When Defendants manufactured the INVOKANA, the state of the industry's scientific knowledge was such that a less risky design was attainable.

182. At the time INVOKANA left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of INVOKANA. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

183. Plaintiff could not, in the reasonable exercise of care, have discovered the defects of INVOKANA and perceived its danger.

184. The defects in INVOKANA were substantial contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

185. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and

services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT X
FRAUDULENT CONCEALMENT

186. Plaintiff restates the allegations set forth above as if fully rewritten herein.

187. Throughout the relevant time period, Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of INVOKANA.

188. Defendants fraudulently concealed information with respect to INVOKANA in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that INVOKANA was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using INVOKANA; and

b. Upon information and belief, Defendants represented that INVOKANA was safer than other alternative medications and fraudulently concealed information which demonstrated that INVOKANA was not safer than alternatives available on the market.

189. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of INVOKANA because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of INVOKANA;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of INVOKANA from Plaintiff.

190. As the designers, manufacturers, sellers, promoters, and/or distributors of INVOKANA, Defendants had unique knowledge and special expertise regarding INVOKANA. This placed them in a position of superiority and influence over Plaintiff and his healthcare providers. As such, Plaintiff and his healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

191. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use INVOKANA.

192. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by INVOKANA was intentional, and the representations made by Defendants were known by them to be false.

193. The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA.

194. Plaintiff, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA

195. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff and his physicians would not have prescribed or ingested the drug.

196. Defendants, by concealment or other action, intentionally prevented Plaintiff and his health care professionals from acquiring material information regarding the lack of safety of INVOKANA, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

197. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct

medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT XI
FRAUD

198. Plaintiff restates the allegations set forth above as if fully rewritten herein.

199. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, his prescribing health care professionals, the health care industry, and consumers that INVOKANA had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

200. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of INVOKANA. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of INVOKANA, such as Plaintiff.

201. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and his prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase INVOKANA, despite the risk of severe life threatening injury, which Defendants knew were caused by the products.

202. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that INVOKANA was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks.

203. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of INVOKANA.

204. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with INVOKANA from physicians and patients, including Plaintiff and his prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the INVOKANA. For example:

a. INVOKANA was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of INVOKANA does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of the INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with INVOKANA was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of INVOKANA was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff relied when ingesting INVOKANA;

f. The limited clinical testing revealed that INVOKANA had an unreasonably high risk of injury, including Plaintiff's injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of INVOKANA, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using INVOKANA could suffer severe kidney damage and sequelae, and would require monitoring while treating with INVOKANA drug therapy; and/or

j. INVOKANA was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

205. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest INVOKANA, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

206. Defendants' intentional concealment and omissions of material fact concerning the safety of INVOKANA was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's prescribing health care professionals to purchase, prescribe, and/or dispense

INVOKANA, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that INVOKANA was a safe and effective diabetes drug therapy.

207. At the time Plaintiff purchased and used INVOKANA, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of INVOKANA's safety and efficacy.

208. Defendants knew and had reason to know that INVOKANA could and would cause serious personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

209. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to use and in fact used INVOKANA, thereby sustaining injuries and damages. Defendants knew and had reason to know that Plaintiff and his health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and his health care professionals would not have prescribed and ingested INVOKANA if the true facts regarding the drug had not been concealed by Defendants.

210. During the marketing and promotion of INVOKANA to health care professionals, neither Defendants nor the co-promoters who were detailing INVOKANA on Defendants' behalf, warned health care professionals, including Plaintiff's prescribing health care professionals, that INVOKANA caused or increased the risk of harm of severe kidney damage.

211. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of INVOKANA.

212. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that INVOKANA was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

213. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of INVOKANA, including Plaintiff. Defendants knew of INVOKANA's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

214. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe kidney damage and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against each the Defendants, and each of them, individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;
5. Punitive damages;
6. Prejudgment interest at the highest lawful rate allowed by law;
7. Interest on the judgment at the highest legal rate from the date of judgment until collected;
8. Attorneys' fees, expenses, and costs of this action; and
9. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff demands trial by jury on all of the triable issues within this Petition.

Dated: October 23, 2015

Respectfully submitted,

/s/ Roger C. Denton

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